ENDOVENOUS ABLATION Vs OPEN SURGERY FOR THE TREATMENT OF VARICOSE VEINS –A COMPARATIVE SYUDY

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment of the regulations

for the award of the degree of

M.Ch. BRANCH - VIII

VASCULAR SURGERY

GOVT. STANLEY MEDICAL COLLEGE & HOSPITAL

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

CHENNAI, INDIA.

AUGUST 2014

CERTIFICATE

This is to certify that this dissertation entitled ***"ENDOVENOUS ABLATION Vs OPEN SURGERY FOR THE TREATMENT OF VARICOSE VEINS – A COMPARATIVE STUDY"*** *is a bonafide work done by* ***Dr. D.N.SHARMILA*** *of* ***Govt. Stanley Medical College and Hospital****,* ***Chennai*** *in partial fulfillment of the university rules and regulations for the award of* ***M.Ch. degree Branch VIII(Vascular Surgery)*** *carried out by her under my guidance and supervision during the academic year* ***2014.***

Name and Signature of the Guide:

Name and signature of the Head of Department:

Name and signature of the Dean:

DECLARATION

I, **Dr.D.N.SHARMILA,** solemnly declare that the dissertation titled **"ENDOVENOUS ABLATION Vs OPEN SURGERY FOR THE TREATMENT OF VARICOSE VEINS – A COMPARATIVE STUDY"** is a bonafide work done by me at Government Stanley Medical College and Hospital during January 2012 to January 2014 under the guidance and supervision of

Prof .Dr. S.R.Subrammaniyan, MS,Mch,FRCS Professor and Head, Department of Vascular surgery, Government Stanley Medical College and Hospital, Chennai.

This dissertation is submitted to Tamil Nadu Dr. M.G.R Medical University, towards partial fulfillment of requirement for the award of **MCh. Degree (Branch – VIII) in Vascular Surgery** three years course.

Place : Chennai **(Dr.D.N.Sharmila)**

Date :

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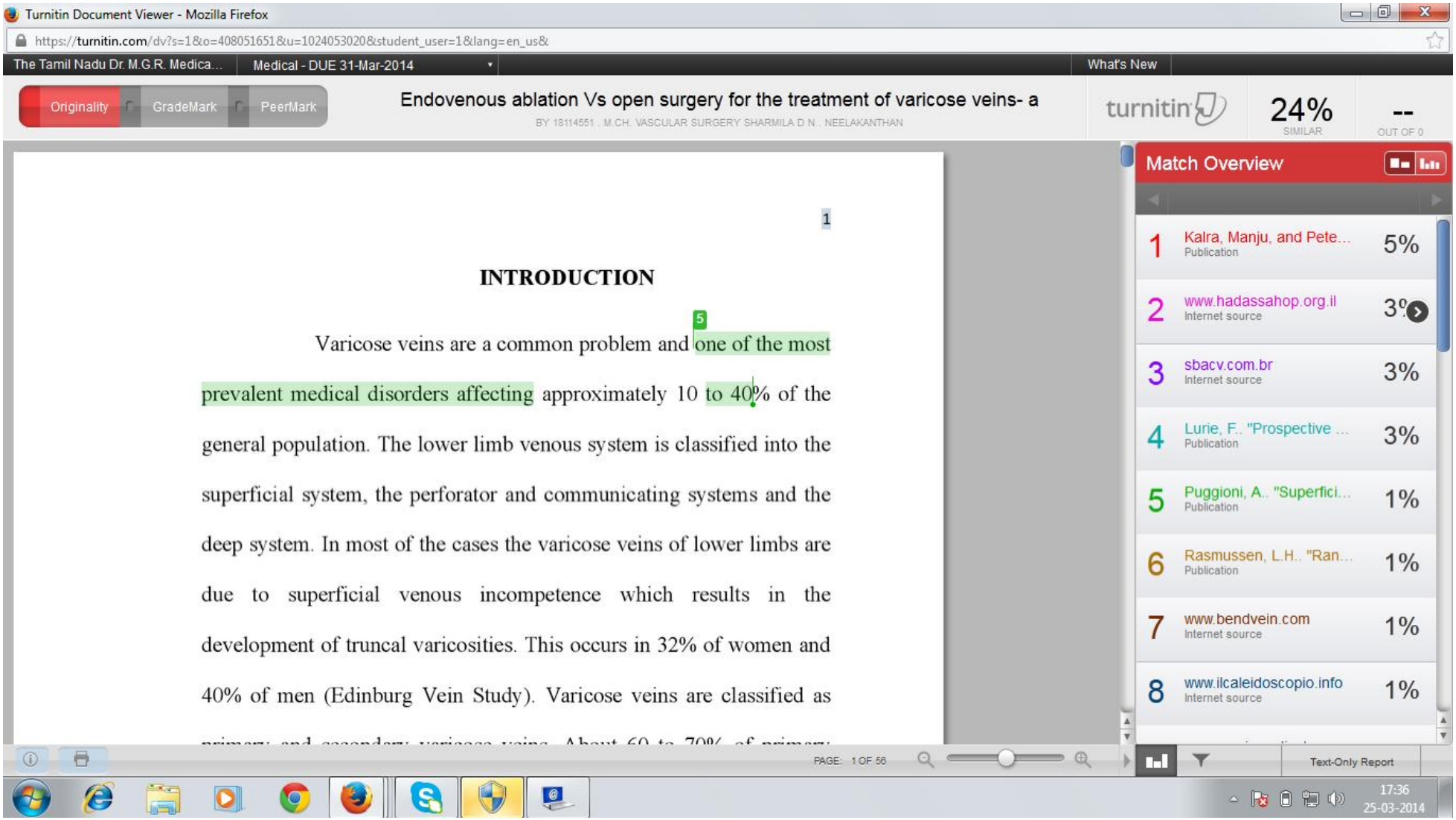
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INTRODUCTION
Varicose veins are a common problem and one of the most prevalent medical disorders affecting approximately 10 to 40% of the general population. The lower limb venous system is classified into the superficial system, the perforator and communicating systems and the deep system. In most of the cases the varicose veins of lower limbs are due to superficial venous incompetence which results in the development of truncal varicosities. This occurs in 32% of women and 40% of men (Edinburg Vein Study). Varicose veins are classified as
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INTRODUCTION

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Varicose veins are a common problem and one of the most prevalent medical disorders affecting approximately 10 to 40% of the general population. The lower limb venous system is classified into the superficial system, the perforator and communicating systems and the deep system. In most of the cases the varicose veins of lower limbs are due to superficial venous incompetence which results in the development of truncal varicosities. This occurs in 32% of women and 40% of men (Edinburg Vein Study). Varicose veins are classified as primary and secondary varicose veins. About 60 to 70% of primary varicose vein develop due to Sapheno Femoral Junction (SFJ) incompetence and Great Saphenous Vein (GSV) reflux while in about 10% it is due to Sapheno Popliteal Junction (SPJ) and Small Saphenous Vein (SSV) incompetence.

Asymptomatic superficial venous reflux occur in 39% of cases and present as cosmetic problem alone, but in the rest of the cases it presents with symptoms such as restless leg, discomfort, ache, heaviness, pain, swelling, hyper pigmentation and eczematous skin changes, ulcers, bleeding, superficial thrombophlebitis and disability such as talipes equino varus.

Treatment of varicose veins is for three main reasons. In the first instance, treatment is to prevent occurrence of complications, such as bleeding, edema, eczema, lipodermatosclerosis and leg ulcers. Leg ulcer treatment is intense and sincere perseverance and endurance is required from both the patient and physician side. It is very expensive owing to its chronicity the duration of treatment required is prolonged. Leg ulcers have a major impact on patients' social life as reflected by the health related quality of life (HRQOL). Secondly, varicose vein treatment also relieves symptoms caused by varicose veins, such as heaviness, tired legs and cramps. Cosmetic reasons are the third reason for treatment.

Treatment begins with the abolition of venous reflux and thereby reducing ambulatory venous hypertension, which is the key point for successful treatment. This can be achieved by surgical ablation or by endovenous ablation of saphenous vein reflux.

Surgical ablation in the form of high ligation of SFJ and stripping of GSV is more than a century old and is considered the gold standard. Lot of innovations in the treatment of varicose veins has developed with the aim of reducing the morbidities associated with the standard surgical procedure. Among them are the endovenous ablations with radio frequency ablation, laser ablation and foam sclerotherapy.

Though the endovenous ablation techniques are a decade old, there are only a few studies in the international literatures comparing these procedures with that of the conventional surgical procedure. Also the national literatures have reported only the case series in the individual endovenous procedures and no comparative study appears to be available so far.

This study compares the outcome of the management of truncal varicose veins in a series of patients presenting to our tertiary care referral centre over a period of one year. The traditional conventional open surgical technique is compared with that of the latest and the newest minimal access endovenous ablative procedures. This comparative study is made feasible because our centre, the Govt. Stanley Medical College and Hospital, Chennai is the first in the government set up to have these endovenous ablation gadgets and provide these minimally invasive endovenous ablations.

AIMS & OBJECTIVES

AIM OF THE STUDY

The purpose of this study was to compare the pre procedural, intra procedural and post procedural assessments and thereby evaluate the efficacy of treatment with endovenous technique in comparison with open technique for abolishing primary superficial venous incompetence and thereby bringing about clinical improvement.

MATERIALS & METHODS

MATERIAL AND METHODS

STUDY DESIGN: The study was designed as a Prospective study comparing procedure related complications and patient recuperation between those undergoing conventional high flush ligation of SFJ (Trendelenburg procedure) and GSV stripping (HL/S) with those undergoing GSV obliteration with endovenous thermal ablation procedure (i.e.) Radio Frequency Ablation (RFA) or LASER ablation (EVLA).

DURATION: January 2012 to January 2014

SETTING: The patients with varicose vein attending the Vascular Surgery OPD of Govt. Stanley Medical College and Hospital, Chennai were enrolled for study. All symptomatic patients were admitted and evaluated with proper clinical history, thorough clinical examination and duplex evaluation. Based on inclusion and exclusion criteria patients were selected and treated accordingly.

The study was approved by the Ethics Committee of the institution.

INCLUSION CRITERIA:

1) Patients in the age group between 20 to 80 years
2) Both males and females were included
3) Patients with varicosity of GSV with grade II reflux and above of the sapheno femoral junction
4) Patients with venous ulcer with GSV varicosity (i.e) CEAP classification C_2 to C_6 (i.e) $C_{2-6}\, E_P\, A_S\, P_R$.

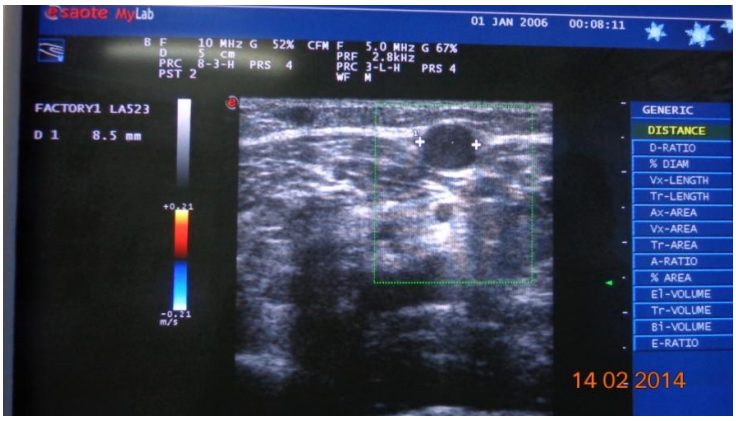
EXCLUSION CRITERIA:

1) Patients with secondary varicose veins due to previous DVT.
2) Patients with recurrent varicose veins
3) Patients with perforator incompetence alone
4) Patients with segmental reflux
5) Female patients with pregnancy
6) Congenital anomalies (E.g.) Klippel Trenaunay Syndrome (KTS)
7) Patients with GSV diameter greater than 1.2cm
8) Patients with ABI less than o.9

9) Patients with general co- morbid conditions like CCF, CRF, open PTB and those mentally unfit to comprehend and give consent to the course of treatment.

INVESTIGATION PROTOCOL:

Rutherford et al described the Venous Clinical Severity Score (VCSS). There are 10 descriptors namely pain, varicose vein, venous edema, skin pigmentation, inflammation, induration, ulcer number, ulcer duration, ulcer size and compressive treatment each of which is ranked as 0 (absent), 1(mild), 2(moderate), or 3(severe). The possible scores are in the range of 0 to 30. The signs and symptoms were recorded using this VCSS score. Also the CEAP classification was applied for varicose vein description which includes the clinical, etiological, anatomical and pathological nature of the disease. Duplex examination was used to record duration of SFJ reflux and diameter of GSV 3 cm below SFJ, at mid thigh and just below knee. Duplex examination was also done to rule out deep venous thrombosis and deep vein reflux. Also base line investigations were performed to identify the risk factors and get them fit for surgery.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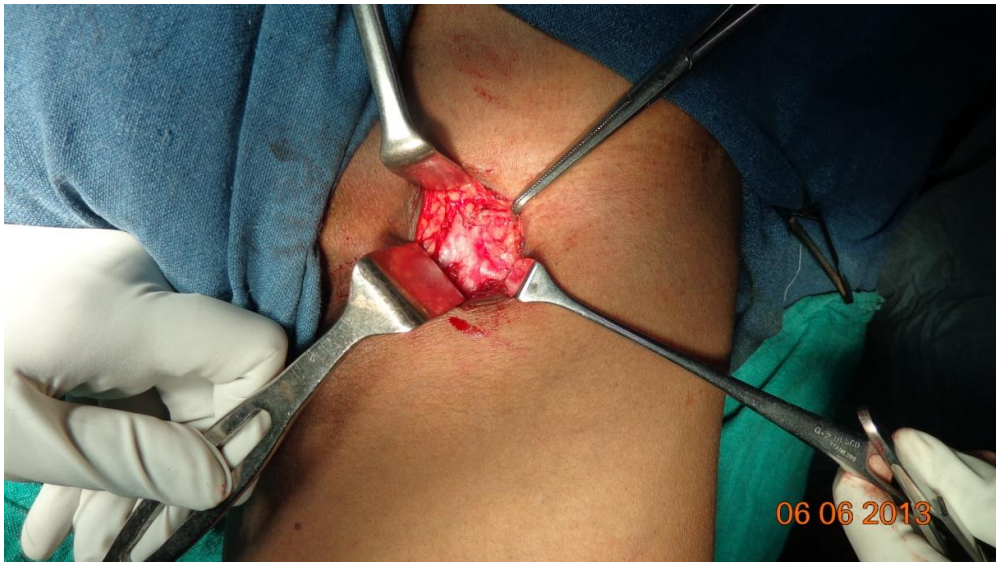
TREATMENT:

The three procedures in this study were done under regional anesthesia.

The surgical procedure of High ligation (Trendelenburg procedure) and GSV stripping was performed through a groin skin crease incision of 4 to 6 cm, with flush ligation of SFJ and division of GSV and all its tributaries near the saphenofemoral junction. The exit of the stripper was at the below knee level or at the ankle if the varicosity extended to the lower leg. The stripper was retrieved through the groin wound with simultaneous application of elastic compression bandage.



In the other arm which included the RFA and EVLT, procedures were performed under duplex guidance. The GSV was accessed by percutaneous puncture with the 7Fr puncture kit or by means of a small cut down at just below knee or in the upper calf. The catheter or the fiber tip was placed 2 cm distal to the SFJ or just distal to the superficial epigastric vein. Tumescent anesthesia, approximately 250-300ml per treatment, was administered peri venously in the saphenous canal under USG guidance.

Radio frequency ablation (segmental ablation) was performed using VNUS CLOSURE FAST system. The EVLA procedure was performed using 1470nm diode laser (BIOLITEC) using continuous mode with 11 to 12W of energy and pull back of 80J/cm. Both RFA and EVLA were performed in limb elevated position.

In both the groups the stab avulsion technique was used to treat the leg perforators and branch varicosities.

At the end of the procedure, the leg was wrapped with sterile absorbent bandages and elastic compression bandages, i.e. elastocrepe bandages (6in) was applied. After the first follow up, i.e. after 72 hours, patients were advised to wear class II compression stockings for the next 12 weeks.

ASSESSMENTS:

Post operative follow up was done within 72 hours, 1 month, and 6 month and at 1 year. Each visit included clinical examination, duplex ultra sound examination and documentation of CEAP staging and VCSS.

In the RFA and EVLA group, the criteria for technical success was considered as obliterated great saphenous vein with lack of flow and absence of saphenous vein was considered as success in HL/S group. Treatment failure or recanalization of great saphenous vein was defined as any open part of the treated vein segment more than 5 cm length. The complication was regarded as minor if no separate treatment was required and major if they required additional treatment or prolongation of hospital stay or led to permanent adverse event. The post operative pain was analyzed using Visual Analogue Scale from 0 to 10 and analgesics prescribed accordingly.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

TREATMENT OF VARICOSE VEINS

Chronic venous disease in a spectrum of anatomical and physiological abnormalities of lower limb veins that is associated with signs and symptoms. The treatment of varicose veins by surgery is aimed at removing the unsightly branch veins. Surgical treatment helps in removing the symptoms of chronic venous disease by reducing or eliminating ambulatory venous hypertension. Non-invasive investigation especially the duplex ultrasound helps to identify the venous system involved, the duration reflux and the status of the deep system and treatment needs to be individualized for each patient based on these results. Depending on the nature of underlying pathophysiology, the elimination of the varicosities can be achieved by either or a combination of the following modes of treatment:

I) Axial superficial venous reflux ablation

1) Surgical excision of saphenous vein reflux

2) Endovenous ablation of saphenous vein reflux

a) Thermal ablation - radiofrequency or laser therapy

b)Chemical ablation - Foam sclerotherapy

II) Varicose veins removal

1) Ambulatory surgical phlebectomy

ABLATION OF AXIAL SUPERFICIAL REFLUX

Axial reflux or gravitational reflux in the great saphenous vein (GSV) or small saphenous vein (SSV) is called the Truncal varicosities. Ablation of these varicosities is indicated in patients in whom reflux at the SFJ or SPJ has been identified on duplex ultrasound. Reflux at saphenofemoral junction occurs in 70% of patients with varicose veins. Atypical reflux at other sites or varicosities without gravitational reflux is found in the remaining 30% of the patients.

SURGICAL ABLATION OF SAPHENOUS VEIN REFLUX

The “gold standard” in the treatment of varicose veins is High ligation at SFJ of the great saphenous vein with its stripping and has been practiced widely. The recent minimally invasive procedures have been compared with this time tested procedure. In the current-day practice stripping of the varicose saphenous vein is largely confined to the thigh because this eliminates the axial reflux, which usually extends only to the knee; thigh perforators are thus disconnected; also this reduces the incidence of saphenous nerve injury associated with stripping of the

below-knee segment of GSV. The perforators in the below knee segment of saphenous vein are not connected directly to the GSV, instead they usually drain into the posterior arch vein of Leonardo, so actually there is no real advantage in stripping the vein up to the ankle. Stripping can be extended to the ankle, in situations where there is gross dilatation of the below-knee segment of the vein with reflux, as demonstrated on duplex ultrasound, usually with the less traumatic inversion technique. Many modifications has occurred in the methods by which the stripping of the GSV is performed like invagination stripping (perforate - invaginate technique, PIN), cryo stripping and to minimize the incidence of haemorrhage, bruising, parasthesia and pain, the use of tumescent anaesthesia with lignocaine and epinephrine in the saphenous canal has come into vogue.

ENDOVENOUS THERMAL ABLATION OF SAPHENOUS VENOUS REFLUX

Mechanism of action

Obliteration of the GSV by endovenous method involves thermal damage of the vein wall. This results in destruction of the intima by a process of selective photothermolysis and denaturation of collagen present in the media. Eventually over time this leads to aseptic fibrotic occlusion of the vein.

Currently there are two widely applied methods available for performing endovenous ablation and they are radiofrequency ablation (RFA) and endovenous laser treatment (EVLT). Continuous and pulsed modes are made available for the laser system in the market by various manufacturers and available in various frequencies as well.

Vein wall damage is brought by Radiofrequency-induced resistive heating and is controlled by the vein wall temperature and the impedance feedback. Upto a depth of 1 mm, direct heating of the vein wall occurs at the site of contact with the catheter, and by conduction, the deeper vein wall heating occurs.

Small profile fibres are available for the laser treatment. Two mechanism is postulated for laser-induced thermal damage. Firstly by indirect heating damage of the vein wall is caused. Intravascular steam-bubble is generated by the laser probe, which heats to a temperature of 1000° C, and this result in thrombotic occlusion of the vein. The second mechanism involves a more direct heating of an empty vein, possibly through a thin film of blood, resulting in indirect damage to the vein wall. In the clinical setting, a combination of the two mechanisms may probably be responsible for the efficacy of EVLT. The lasers probes that are available at present include haemoglobin-specific laser wavelengths (810, 940, and 980 nm) and water-specific laser wavelengths (1320, 1319 nm and 1470nm), and their mode of

action is of debatable differences. For the homogeneous distribution of the thermal damage throughout the inner vein wall, the intra vascular blood is responsible.

LONG AND SHORT TERM RESULTS OF SUPERFICIAL REFLUX ABLATION

The Short term results

The most accepted surgical method of ablation of superficial reflux is stripping of the great saphenous vein up to the level of the knee. This is combined with high ligation and disconnection of all tributaries in the groin. Inversion stripping is less traumatic than conventional stripping. It is shown to be associated with minimal blood loss and decreased incidence of saphenous neuralgia, which is confirmed in a recent randomized, controlled trial[13]. Compared to stripping of the GSV, recurrent varicose veins is associated more commonly with high ligation alone, because this operation fails to eliminate the axial reflux[13]. Also as the connecting thigh perforators feed the saphenous vein, the saphenous vein remains patent entirely or partly.

In comparison to conventional stripping, two recent prospective, randomized trials evaluating the advantages of cryo stripping with conventional stripping demonstrated a shorter operative time and fewer

bruising but similar postoperative pain, mobility, complications, and improvement in quality of life measurement that was done objectively[13]. After the advent of endovenous ablation techniques, most of the recent studies have started to concentrate on comparing these endovenous techniques with the traditional high ligation and stripping. With the minimally invasive endovenous procedures most of the practioners have observed better patient acceptance and experienced decreased discomfort in the performance of procedures.

Clinically the benefits of RFA over stripping has been shown in four separate randomized clinical studies comparing this technique with conventional stripping[8,9,26,28,27,21]. One among them is the **EVOLVeS** study. It was a prospective, multicenter, randomized study that included 85 patients (86 limbs) randomized to radio frequency ablation versus SFJ ligation and stripping. Closure resulted in initial occlusion rate of 91%, earlier return to work, less postoperative pain, and better early quality-of-life scores[8,9]. Complication rates were similar in both the RFA and conventional stripping groups, but the average post operative pain was found to be significantly less severe in the radio frequency obliteration group. Absence from work was also shorter and physical function was restored faster than in the stripping group, resulting to be potentially cost effective factor for the society[26]. With increasing experience, the clinical outcome of RFA was further evaluated

objectively and a significant improvement in the venous severity score was observed[21].

Like wise, the early success of ablation of the refluxing vein has been reported as 90% to 98% of patients with EVLA[13,30]. Large, single-centre experiences with EVLA have demonstrated early occlusion rates of 97% to 98% and showed occlusion rates in 93% of limbs at 3 years[30]. In an international registry of 5262 patients, 96% successful occlusion was reported by Kabnick following GSV ablation with the 980-nm laser. Also a similar efficacy in ablating the GSV is reported with other wavelengths[12,30]. There are evidences that shows that the water specific laser wavelengths (1320 and 1319 nm) result in less postoperative discomfort; also there are no definite evidence that supports the use of one laser wavelength over another[12,25]. In addition following laser ablation, a statistically significant improvement in the CEAP classification has been documented. In the only prospective, randomized trial that compared EVLT with stripping which was performed under tumescent anaesthesia in 121 patients, Rasmussen et al. reported higher postoperative pain scores in the surgical group. Anyhow there was no significant difference in analgesics consumed, time to return to normal activity, or to work. In early post procedure period there was detoriation of all quality of life measure scores but by 3 months in both groups a significant improvement was noted [21].

The Long-Term Results

In spite of the initial morbidity of the procedure long lasting relief from symptoms has been observed with the traditional surgical treatment of varicose veins with high ligation and stripping. The superior long-term outcome of stripping over high ligation alone or sclerotherapy or a combination of the two has been confirmed in prospective, randomized trials[32,33]. At a mean follow-up of 3 to 5 years, 71% to 90% of patients who have undergone stripping had functional improvement and improved hemodynamic parameters. The SF-36 and venous disease-specific (Aberdeen Varicose Vein Severity Score) questionnaires[34] have also demonstrated a significant improvement in quality of life.

In a recent randomized, prospective clinical trial, the **ESCHAR (Effect of Surgery and Compression on Healing and Recurrence) trial**, evaluated stripping with or without phlebectomy and conservative treatment in 246 patients with uncomplicated varicose veins. At the end of 2 year follow up, it found significant improvement in symptoms and quality of life in surgically treated patients[35].

Following high ligation and stripping there is a guaranteed abolition of the great saphenous vein, but the fate of the treated vein following endovenous ablation yet needs to be monitored and

evaluated. Mid- and long-term results following RFA and EVLT has become available recently. The duplex ultrasound has demonstrated that, usually at 1 year and thereafter, there is complete disappearance of the GSV or remains as minimal residual fibrous cord with no flow detectable.

Nicolini has reported a 3-year result following RFA in 330 limbs. The total occlusion rate was 75%, 18% was partial occlusion (less than 5 cm of open segment) , and 7% incomplete occlusion (more than 5 cm of open segment) [36].

Merchant and Pichot in 2005[31] published the long-term results of the Closure Study Group at 5 years following RFA. The multicenter, prospective registry comprised data from more than 1200 limbs treated. It reported occlusion rates at the end of 1, 2, and 5 years as 87.1%, 88.2%, and 87.2%, respectively.

In the same study in 185 limbs, using Duplex ultrasound one of the following modes of anatomical failure was identified:

a)Type I failure: (nonocclusion) - (12.4%) - is the failure of veins to occlude initially and never occluded during the follow-up.

b)Type II failure: (recanalization) - (69.7%) - refers to veins that occluded initially , partly or completely, but recanalized at a later date.

c)Type III failure: (groin reflux) - (17.8%) - is the situation where the vein trunk remained occluded, but by involvement of an accessory vein, the reflux occurred at the groin region.

Importantly the anatomical failure did not necessarily result in clinical failure. In most patients significant relief from symptoms of pain, fatigue, and edema was observed. 70% to 80% of those with anatomical failure remained asymptomatic, whereas 85% to 94% of those with anatomical success remained asymptomatic. Identification of Type II and type III anatomical failures is important as they are the risk factors for recurrence of varicose vein.

A meta- analysis on Endovenous therapies of lower extremity varicosities, conducted by a systematic review of Medline, Cochrane Library, and Cinahl, was performed to identify studies on the effectiveness of the four therapies up to February 2007. Of the 119 studies that were retrieved, 64 (53.8%) were eligible and assessed 12, 320 limbs. Average follow up was 32.2 months. After 3 years, the estimated pooled success rates for stripping, foam sclerotherapy, RFA and EVLA was 78% (70-84%), 77% (69-74%), 84% (75-90%) and 94% (87-98%) respectively. After adjusting for follow up, foam therapy and RFA were found to be as effective as surgical therapy. EVLA was significantly more effective when compared to stripping, foam therapy and RFA. The study concluded that in the absence of

large, comparative randomized clinical trials with long term follow ups, for the treatment of lower extremity varicose veins the minimally invasive endovenous techniques appear to be as effective as surgery.

The **RELACS Study** compared the effectiveness of endovenous laser ablation and high ligation with stripping of the great saphenous vein and gave a two year result of a randomized clinical trial. It is the largest randomized trial that compares an endovenous approach for the obliteration of great saphenous vein with high ligation and stripping. The results are overall compatible with other studies, suggesting minimal difference between EVLA and HL/S in terms of early and late outcomes.

As a whole, regarding endovenous ablation, a review of the literature reveals about 10 randomized trials since2005. Taken as a whole, these trials demonstrates relatively equal efficacy of all techniques for treatment of axial vein reflux, with regard to post operative pain and early return to work and normal activities, with only a minor advantage for RFA .

A Randomized clinical trial comparing EVLA, RFA, Foam sclerotherapy and surgical stripping for great saphenous varicose veins with 3-year follow up involved a total of 500 patients (580 legs). They were randomized to one of the three endovenous treatment or high ligation and stripping. Follow up included clinical, duplex ultrasound

examinations, VCSS and QOL questionnaires. The study concluded that all the four treatment modalities for axial vein reflux were efficacious and resulted in similar improvement in VCSS and QOL. But, more recanalization and reoperations were seen after ultra sonogram guided foam sclera therapy.

An article on Endovenous laser therapy in the Journal of Biophotonics reported that with latest innovative technologies, EVLA treatment appears to be getting closer to the goal of standardizing an effective method in the treatment of varicose veins. It proposed that further controlled studies were required to compare the results of an optimized endovenous laser treatment with other endo thermal methods of treatment and the conventional open surgery of HL/S.

From the Journal of International Angiology, **The first 1000 cases of Italian Endovenous- Laser Working Group (IEWG). Rationale , and long term outcomes for the 1999-2003 period,** the conclusion was that EVLA appears to be a good solution for all patients with anatomic and hemodynamic patterns instead of saphenous vein surgery. It also concluded that endovenous ablation of great and short saphenous vein with a 1470nm diode laser is a minimally invasive, safe and efficient therapeutic option with high rate of success.

OBSERVATION AND

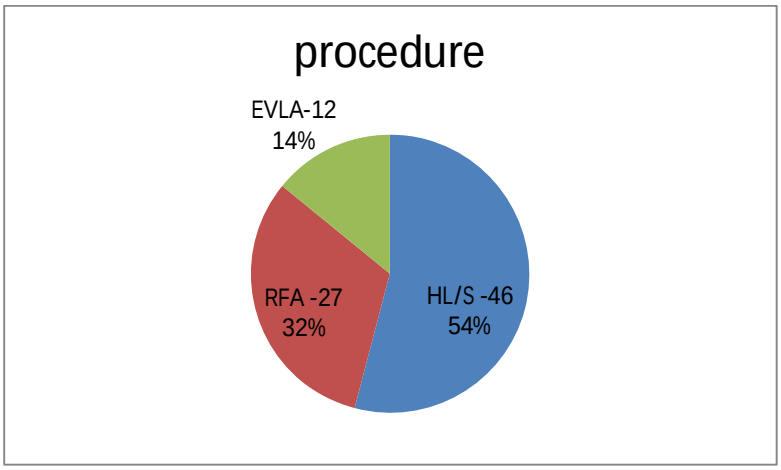
RESULTS

OBSERVATION AND RESULTS

Patients were enrolled from January 2012 to January 2013 and the follow up was continued till January 2014. Totally 85 cases were enrolled out of which 46 patients underwent high ligation and stripping and 39 patients underwent endovenous ablation. Among endovenous ablation group 27 patients underwent radiofrequency ablation and 12 patients underwent EVLA.

TABLE 1: TREATMENT DISTRIBUTION

	Procedure			Total
		Endovenous		
	HL/S	RFA	EVLA	85
Cases	46	27	12	
Total	46	39		85



Of the 85 cases treated 74 patients were males and 11 patients were females. Out of the 74 males, 39 patients underwent HL/S, 23 patients underwent RFA, and 12 patients underwent EVLA. Among the 11 female cases, HL/S was performed in 7 patients and RFA in 4 patients.

TABLE 2: SEX INCIDENCE

Patients	Procedure	Frequency		Percent
Male	HL/S	39	74	87%
	RFA	23		
	EVLA	12		
Female	HL/S	7	11	13%
	RFA	4		
	EVLA	0		
Total		85		100%

SEX INCIDENCE

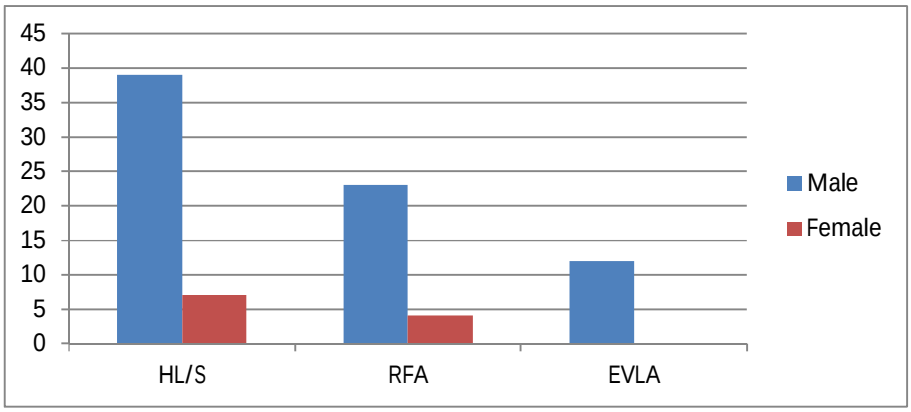
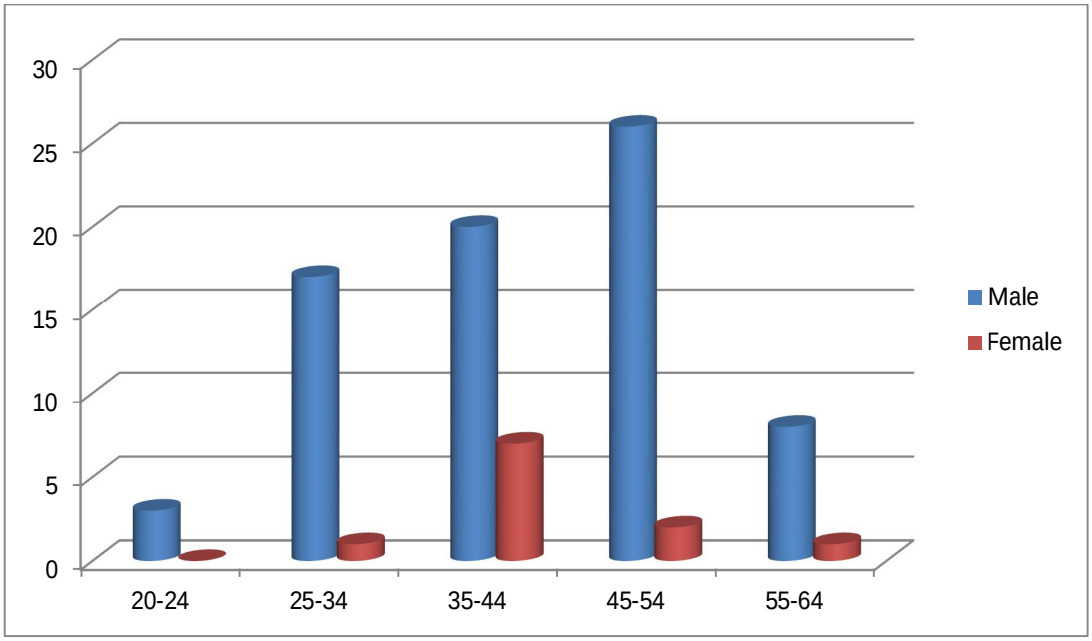


TABLE 3: AGE DISTRIBUTION

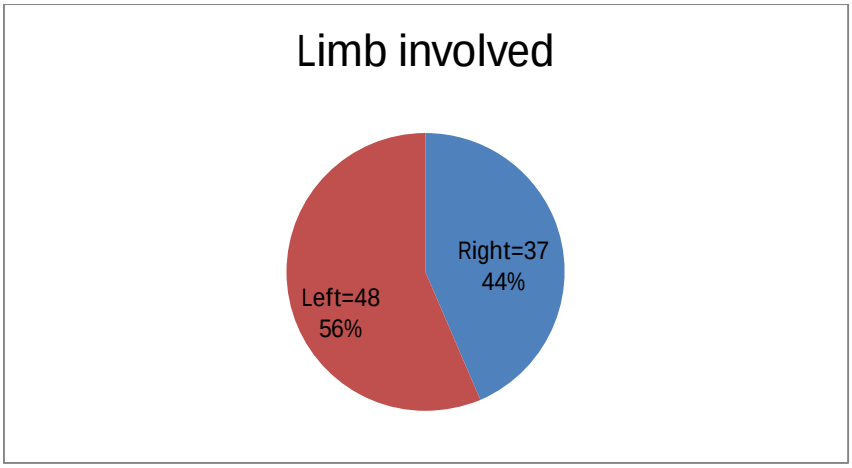
Age in yr	20-24	25-34	35-44	45-54	55-64	Total
Male	3	17	20	26	8	74
Female	0	1	7	2	1	11
Total	3	18	27	28	9	85

Table 3 shows the age group involved in this study. The age group commonly affected both in males and females were found to be in the range of 35 to 55 years.

AGE DISTRIBUTION



85 limbs were treated in85 patients. The study did not have any bilateral limb treated in the same sitting. Of the 85 limbs, 48 involved left and 37 involved right lower limbs.

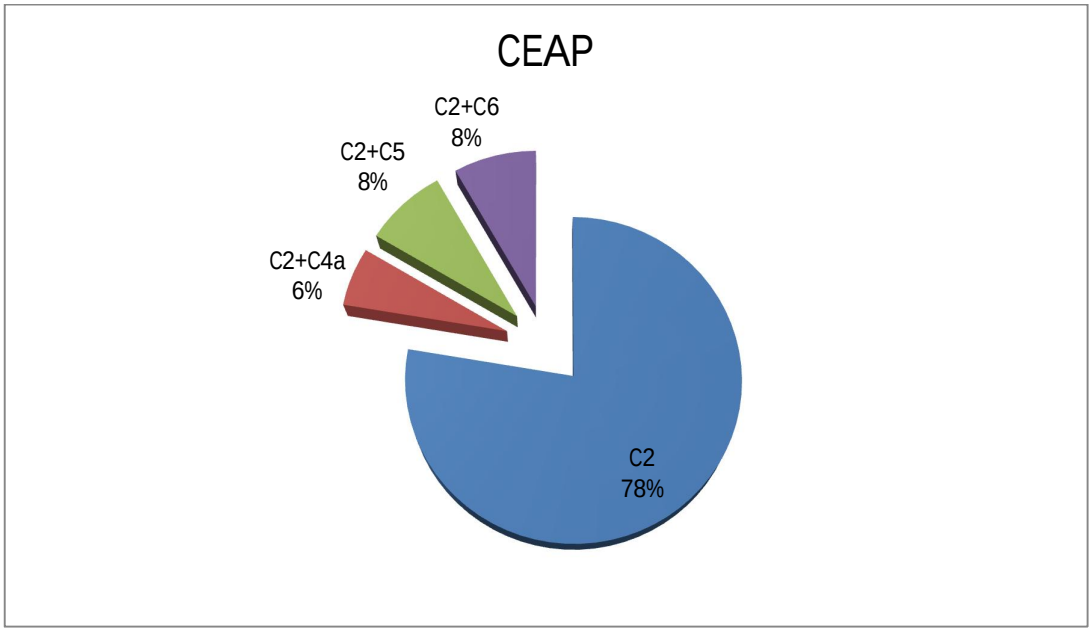


CEAP CLINICAL CLASSIFICATION:

The varicose vein patients who were symptomatic were categorized according to CEAP classification.

TABLE 4: CEAP CLINICAL STAGING

CEAP	HL/S	RFA	EVLA	Total
C2	37	20	9	66
C2+C4a	4	1	0	5
C2+C5	4	3	0	7
C2+C6	1	3	3	7
Total	46	27	12	85



78% (n=66) of treated patients had varicose vein alone that were symptomatic. The symptom included restless legs, heaviness, leg ache or edema of ankles towards evening which subsided on overnight rest. There was no case of varicose vein operated for cosmetic reason alone. Of the 7 patients with active ulcer one patient underwent HL/S, 3 patients underwent RFA and 3 patients underwent EVLA. The sizes of the ulcer were between 2-4 cm averaging 3 cm. The average time taken for ulcer to heal was 3 weeks to 3 months. There was no ulcer recurrence in the one year period of follow up.

C2

C2,4a

C2,4a,5

C2,4a,6

All the procedures were performed under regional anesthesia. Pre operative vein mapping was done under duplex guidance.

In technique comparisons, vein access of the distal extent of saphenous vein in the leg was with cut down in all the 46 (100%)limbs in HL/S group and in 46% (18 of 39) of limbs in endovenous group. The other 21 limbs in endovenous group were accessed via percutaneous puncture of GSV in the calf using 7Fr puncture kit under ultra sound guidance.

Procedural complications were infrequent in both the treatment groups. Phlebectomies of superficial leg varicosities were performed by stab avulsion technique in all patients in both the groups.

Immediate success on the day of treatment was reported in 100% of all treated groups.

The complications and adverse events were evaluated in the peri operative period.

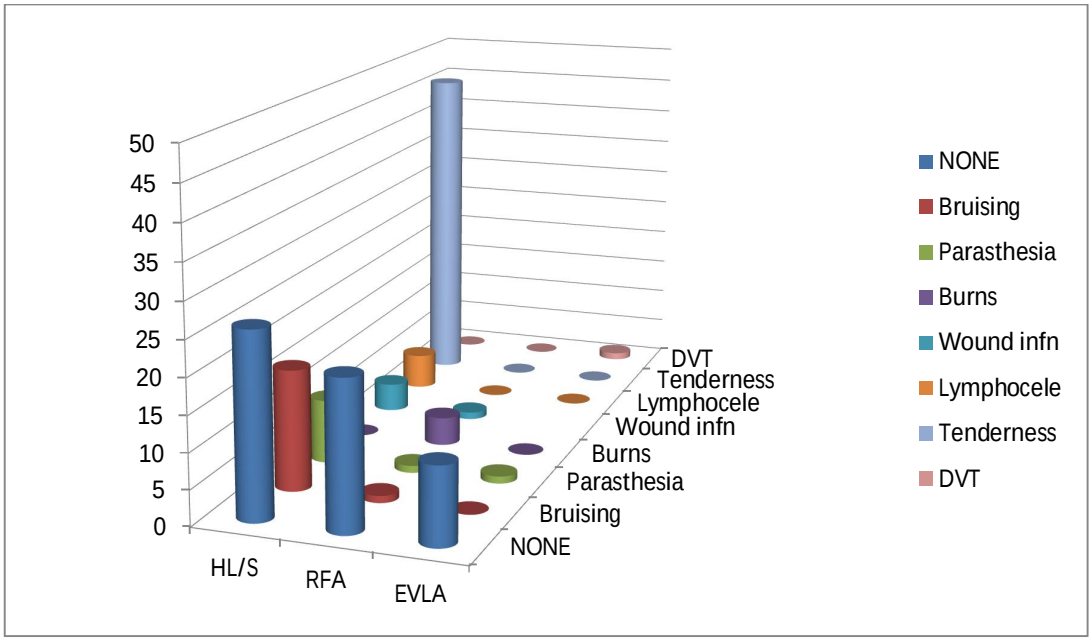
TABLE 6: COMPLICATIONS AND ADVERSE EVENTS

complications	HL/S		RFA		EVLA		P-Value	
	n	%	n	%	n	%	HL/S Vs ENDO	RFA Vs EVLA
None	26	56.5	21	77.7	11	91.6	0.0289	0.3464
Bruising	17	36.95	1	3.7	0	0	0.0005	0.6923
Parasthesia	9	19.56	1	3.7	1	8.3	0.1312	0.6154
Burns	0	0	4	14.8	0	0	0.0110	0.2134
Wound infn.	4	8.69	1	3.7	0	0	0.4406	0.6923
Lymphocele	5	10.8	0	0	0	0	0.1052	-
Tenderness	46	100	0	0	0	0	<0.0001	-
DVT	0	0	0	0	1	8.3	0.0461	0.3077
“pulling”sensation	0	0	13	48.1	3	25		

To calculate the p-Value Chi-Square test is applied.

P-value less than 0.05 was considered statistically significant.

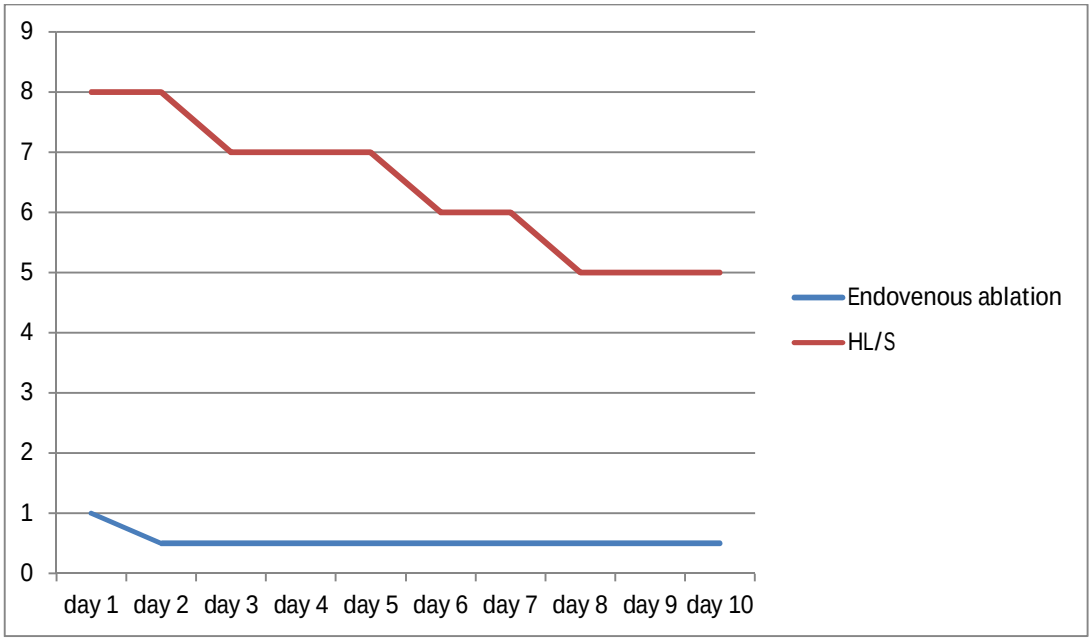
COMPLICATIONS AND ADVERSE EVENTS:



The peri operative complications were observed maximally in the HL/S group (P value=0.0001). All patients had induration and tenderness in the groin wound from the immediate post operative period to 2 to 3 weeks post op. The same was not a complaint in the endovenous group as no incision was made at the groin.

Subjective assessment of pain was done using Visual Analog Scale from 0 to 10 during the first 10 days and during periodic follow up. The pain score was higher initially and in the subsequent 2 weeks after HL/S compared to endovenous ablation.

PLOT OF PAIN SCORE



The line chart clearly shows the advantage of pain score for endovenous ablation.

However, another unique observation noted was cord like pulling sensation or tethered sensation along the treated GSV course in the endovascular group which was observed after 48 hours of treatment and persisted in a few patients (n=8, 29.62%) until the third follow up visit. Patients treated with RFA showed this pronounced finding (n=13, 48.1%) compared to only 25% (n=3) in those treated with EVLA.

The other major complication was the wound infection which occurred at the groin in 4patients (8.69%) treated with HL/S and at the

cut down site in 1 patient (3.7%) treated with RFA. The same was treated with parenteral antibiotics, analgesics and local wound care.

Another related problem regarding groin dissection was lymphocele which was observed in 5 patients (10.8%) in HL/S group. Lymphocele were small measuring 5 to 10cc as measured while duplex examination, which were managed conservatively.

Skin burns were observed in 4 (14.8%) patients in the RFA group and non in the EVLA group. Burns were superficial with minimal surrounding erythema. All were managed conservatively.

Bruising was observed in 17 (36.95%) patients who underwent HL/S and in one patient (3.7%) in RFA treatment group (P Value=0.0005). The bruising resolved in 3 weeks time and was not

observed in most of the patients during the first follow up visit at one month.

Numbness and parasthesia along the distribution of saphenous nerve was seen in 9 (19.56%) patients who underwent HL/S and in one (3.7%) patient who underwent RFA. The paresthesia resolved in 3 months time in RFA treated patient whereas parasthesia was persistent until 6 months in the HL/S patients.

Deep venous thrombosis was observed on the second post operative day in one patient who underwent EVLA. The incidence of DVT in this study was 2.56% (P Value=0.04). In the rest of the patients who underwent endovenous ablation there was no extension of thrombus proximal to the superficial epigastric vein or the occurrence of DVT as

observed by duplex examination within first 72 hours. The one symptomatic patient was continued hospitalization for 2 weeks and managed with parenteral anticoagulation, analgesics and limb elevation. The patient was subsequently swapped to oral anticoagulation and followed up on outpatient basis. The occurrence of DVT in this patient was extension of the thrombus into the femoral vein beyond SFJ. This finding is not infrequent after EVLA of GSV as has been reported in the J Vasc Surg 2005;41:130-5 (Extension of saphenous thrombus into the femoral vein: a potential complication of new endovenous ablation techniques).

The average duration of hospital stay was also evaluated and also compared. It was observed that the average duration of hospital stay was 7 days in the HL/S group and 2 days in endovenous group.

	DAYS													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
HL/S					3		40	1		2				
RFA		20	3		1		2					1		
EVLA	3	4	4											1

The outcome or the procedural success was assessed by clinical improvement in CEAP classification, including the rate of ulcer healing and improvement in VCSS and by duplex examination.

Both treatment groups had 100% procedural success rate with the extirpation of the varicosed segment of veins and obliteration of refluxing segments of veins in HL/S and endovenous groups respectively with disappearance of clinically visible veins.

The Venous Clinical Severity scores improved significantly from a mean of 5.4 (range, 1 to 16) and 3.1 (range, 1 to 12) to 0.84 (range, 0

to 4) and 0.435 (range, 0 to 4) at the third visit (6 month) follow up in the HL/S and endovenous group respectively.

TABLE 7: OUTCOME ANALYSIS

Measures		Pretreatment	72 hrs	1 month	6 month	1 yrs
VCSS	HL/S	4.9	-	-	0.8	-
	ENDO	3.1	-	-	0.4	-

Group Statistics at 6 month					
	Group	N	Mean	Std. Dev	P-Value
VCSS	HL/S	46	0.91	0.839	0.005
	ENDO	39	0.41	0.751	

Student – t (Independent samples) Test is applied to calculate the P-Value

The mean ulcer size was 4cm (n=1) in HL/S, 3cm (n=3) in RFA and 2.33cm (n=3) in EVLA group with rate of ulcer healing of 75%, 83.33% and 82.84% respectively at the end of 1 month and 100% in all groups at the end of 6 months.

TABLE 8: OUTCOME ANALYSIS

Measures		Pretreatment	72 hrs	1 month	6 month	1 yrs
ULCER SIZE	HL/S	4cm	4cm	1cm	0	-
	RFA	3cm	3cm	0.5cm	0	-
	EVLA	2.33cm	2.33cm	0.833	0	-

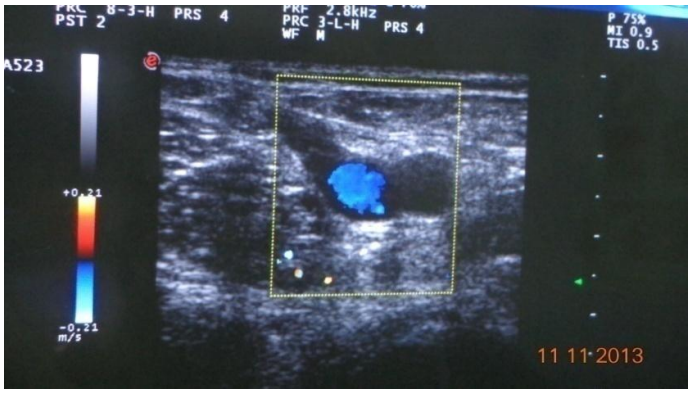
Statistics		
Ulcer size		
RFA	N	3
	Mean	0.6667
	Median	0.5000
	Std. Deviation	0.28868
EVLA	N	3
	Mean	0.8333
	Median	1.0000
	Std. Deviation	0.28868

P-Value for ulcer size at 1 month between RFA and EVLA P= 0.700

Mann – Whitney U-Test is applied to calculate the P-Value.

The ultrasound follow up in the post operative period was used to compare the results for length of GSV occlusion, residual patent segments and reflux findings and also the status of deep veins. Absence of GSV and reflux at SFJ was noted in all the treated limbs in HL/S group (100%, n=46). The treatment success was defined as closed great saphenous vein with lack of flow i.e. less than 5cm of proximal patent vein and no reflux in the patent segment in the endovenous group. All

the patients in the endovenous group (100%, n=39) fitted into the technical success criteria and remained closed till the end of follow up at the end of one year.



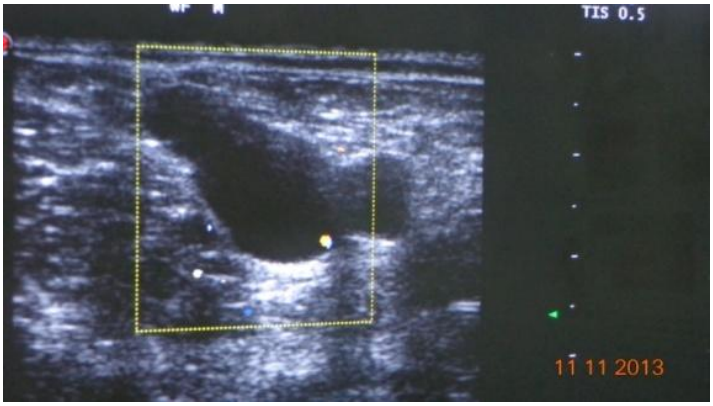


TABLE 9: OUTCOME ANALYSIS

Measures		Pretreatment	72 hrs	1 month	6 month	1 yrs
CEAP	HL/S	C2 to C6	Co	Co	Co	Co
	ENDO	C2 to C6	Co	Co	Co	Co
VCSS	HL/S	5.4	-	-	0.84	-
	ENDO	3.1	-	-	0.435	-
ULCER SIZE	HL/S	4cm	4cm	1cm	0	-
	RFA	3cm	3cm	0.5cm	0	-
	EVLA	2.33cm	2.33	0.433	0	-
GSV STATUS	HL/S	Varicose veins	absent	absent	absent	Absent
	ENDO	Varicose veins	closed	closed	Closed	Closed

DISCUSSION

DISCUSSION

The conventional treatment for the patients with symptomatic incompetent superficial veins is best done by removing the refluxing saphenous vein from the saphenofemoral junction to a level at the knee or up to the leg, with individual ligation of the named saphenous branches at the groin.

High ligation(Trendelenberg) and stripping is considered to be the standard treatment of varicose veins, as it has highest rate of initial rate of success and lowest rate of recurrence.[22,23] Any other alternative techniques to high ligation and stripping of saphenous vein should have the same or a better outcome, without any associated morbidity. The newer techniques are minimally invasive endovascular obliteration of the vein with the radiofrequency or laser generated heating probes placed inside the vein through the percutaneous puncture or by cut down in the upper leg.

The aim of our study was to compare the efficacy of the treatment with endovenous technique with the standard open technique (high ligation and stripping) for abolishing superficial venous incompetence and thereby bringing about symptomatic relief.

The study was designed as prospective study with the assessment of operative adverse events and post operative sequelae and recovery of the patient for a short term of one year.

In this study, 85 patients were enrolled out of which 74 were males and 11 were females. Though the female incidence with varicose vein is higher in general population, the poor participation of females in our study arm could probably be that they preferred a trial compression therapy during the period of enrollment.

46(54%) patients underwent high ligation and stripping and 39(46%) patients underwent endovenous obliteration by means of radiofrequency ablation [27(32%)] and laser ablation [12(14%)]. The study sample was well matched with the other randomized studies.[8,12,13,21] The mean age of incidence was 40±5 years in females and 50±5years in males.[8,21]

Clinical classification of the varicose veins were done based on CEAP classification and among those who underwent treatment 78%(n=66) belonged to C2, 6%(n=5) belonged to $C_{2,4a}$, 8%(n=7) belonged to $C_{2,5}$ and 8%(n=7) belonged to $C_{2,6}$.

In this study, HL/S and endovenous thermal ablation were found to be equally efficient in eliminating the incompetent saphenous vein as

demonstrated by duplex examination within 72 hours of procedure with the success rate of 100%. The similar success rate have been shown in various studies; randomized trial comparing endovenous laser ablation of GSV with HL/S in patients with varicose veins: short term results from the American Venous Forum(100%)[21], J Vasc Surg.2009: In a meta analysis a success rate of 93.3% for EVLA, 87.5% for RFA and 80.4% for HL/S[19], J of cardiovascular surgery 2005(96 to 100%) was observed. The mean follow up period in above literature quoted were between 6 months to 3 years.

The occurrence of adverse events was minimum and not different among the groups. Apart from bruising, which was statistically more (P Value=0.0005, <0.05) in the HL/S group (39.95%) compared to RFA (3.7%) and none in EVLA, the bruising event was low in our study compared to other studies which showed 52% in HL/S and 27% in RFA (J Vasc Surg 2003) and 25% and 11% in HL/S and EVLA respectively (J Vasc Surg 2007).

4 patients in HL/S (8.69%) and 1 patient in RFA (3.7%) underwent treatment for infection at groin and cut down site respectively. Such infection rate was low compared with another study, where infection was reported in 13.7% of patients after high ligation of saphenous vein (J R Coll Surg Edinb 1991). The occurrence of

lymphocele was high (10.86%) in our study compared to other study (2.8%)(J Vasc Surg 2003) in the HL/S group.

In our study the incidence of parasthesia was higher in HL/S group (19.56%) compared to RFA (3.7%) and EVLA (8.3%) where as the other study from literature showed higher incidence in RFA (23.3%) and EVLA (2%) compared to HL/S (13.9%)[8,21]. Similar incidence of parasthesia in HL/S (15%), RFA (3.8%) and EVLA (7.8%)[7] was observed in another study.

Burns as a procedural complication occurred in 4 (14.8%) patients in RFA group and none (0%) in EVLA group. Skin burns have been reported in the literature using the 1064nm Nd:YAG laser (Lasers Surg Med 2002) and none with the diode Lasers (early results of various laser ablation studies)[2]. The incidence of skin burns has been reported as 2-4% in the results of various RFA studies[2].

Although DVT has been reported in up to 5.6% of laser patients and up to 16% in RFA patients[1,2,7] , our study had one incidence of DVT (8.3%) in EVLA group which was managed successfully with anticoagulation.

Post operative pain in the leg was higher after HL/S compared with endovenous procedures as indicated by statistically significant

differences in pain score as well as by the presence of tenderness (P<0.0001) in all 46 patients who underwent HL/S. The pain was usually located to the thigh. However a paired study comparing EVLA (810nm laser) and HL/S performed with regional anesthesia found no difference in pain between the groups, but the patients indicated more benefit in the leg treated with laser in addition to less bruising and edema (Dermatol Surg 2005). The tumescent fluid placed within the saphenous canal under ultra sound guidance may have probably reduced the immediate post operative pain in the endovenous group as there was no significant difference in pain score in the subsequent follow up visits in both the groups.

Similarly the rate of ulcer healing was observed to be slightly better in the endovenous group with healing rate of 83.33% and 82.84% for RFA and EVLA at the end of one month and 75% in the HL/S group, though they are not statistically significant (P=0.700, >0.05). The rate of ulcer healing was not separately observed in most of the randomized studies as this parameter was included as one of the component of the VCSS. As expected, the VCSS improved similarly in both the groups. The mean scores improved significantly (P<0.05) after operation, falling from a mean of 5.4 (range 1to16) and 3.1 (range

1to12) to 0.84 (range 0 to 7) and 0.435 (range 0 to 4) at 6 months in the HL/S and endovenous group respectively.

Also the average duration of hospital stay was considerably less in the endovenous group averaging 2 days compared to 7 days in the HL/S group with return to normal activities in less than 2 days in endovenous group and averaging 5 days in HL/S group. The same was observed in other studies where the return to normal activities were 3.5 (0-8) in EVLA and 14 (3-28) days in HL/S groups[7] and 0 to 3 days in RFA Vs 3 to 15 days in HL/S group[8].

The last decade has seen the evolution of new minimally invasive methods including radiofrequency ablation, endovenous laser ablation and foam sclerotherapy for the treatment of GSV incompetency as an alternative to conventional high ligation and stripping. There are several randomized controlled trials involving these new methods that are available in the literature. A few of them are quoted here for application of interpretation of the study conducted here :

1) In one randomized controlled trial which compared laser ablation with open surgery, there were no difference in pain scores, but a significantly less bruising and swelling occurred following EVL ablation[25].

2) There are five RCTs which compare RFA with EVLA. The trials showed similar complication and closure rate in both groups[13]. Kabnick concluded that the most current RFA and jacket tipped EVLA methods and devices are indistinguishable in terms of efficacy and short term results. These procedures present no significant differences from the patient's point of view as the procedure time and use of tumescent anesthesia was same.
3) The four RCTs comparing radio frequency ablation with high ligation and stripping demonstrated that radio frequency ablation have significant advantages, that included faster recovery, less operative pain, fewer adverse events and improved quality of life scores[8,9,26,27] when compared to conventional stripping.

4) One RCT compared open surgery Vs EVLA Vs RFA Vs ultrasound guided foam sclera therapy (UGFS)[13]. The study observed better quality of life (SF36), and also lower pain score ($P<0.001$) and shorter time away from work ($P<0.001$) in RFA and UGFS groups. Also GSV occlusion was better with HL/S, RFA and EVLA than

with UGFS (P less than 0.0001). There was no significant difference in clinical recurrence in all the treatment groups.

The May 2011 issue of JVS published the final conclusions of Society for Vascular Surgery/ American Venous Forum guidelines for treatment of varicose veins. Owing to the minimally invasive nature as well as similar or better early term and equivalent midterm results, endovenous thermal ablation is to be recommended as the first line of treatment of varicose veins associated with axial reflux over open surgery [13].

Table : 10; Comparison of parameters among various studies:-

Srl No		Our Study				AVF-EVLA Vs HL/S			EVOL VeS			Other Studies		
		HL/S	RFA	EVLA	P	HL/S	EVLA	P	HL/S	RFO	P	HL/S	EVA	P
1	Study Sample	n=46	n=27	n=12	-	59	62	-	36	40	-	-	-	-
2	Follow-up Period	1 year	1 year	1 year	-	6 month	6 months	-	4 months	4 months	-	6 months to 3 years	6 months to 3 years	-
3	Procedures Success Rate	100%	100%	100%	-	97%	96%	-	100%	95%	-	95 – 99%	92 – 98%	-
4	Bruesing	36.95%	4%	-	<0.05	25%	11%	-	52%	27%	-	-	-	-
5	Burns	-	14.80%	-	>0.05	-	-	-	-	-	-	-	2 – 4 %	-
6	Paraesthesia	19.56%	3.70%	8.30%	>0.05	8%	2%	-	5.60%	11.40%	-	15%	3.80%	7.80%
7	Wound Infection	8.69	3.7%	-	>0.05	2%	-	-	5.60%	-	-	13.70%	-	-
8	DVT	-	-	8.30%	>0.05	-	-	-	-	-	-	-	5.6-16%	-
9	Pain / Tenderness	100%	-	-	<0.05	24%	3.70%	<0.05	25%	4.50%	<0.01	-	-	-
10	Rate of wound healing	75%	82%	83%	0.7	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
11	VCSS	0.8	0.35	0.5	<0.05	0.2	0.4	-	0.7	0.6	<0.03	-	-	-
12	Hospital Stay / Return to Normal Activities	7 days	3 days	2 days	<0.05	14 days	3.5 days	<0.05	12.4 days	4.7 days	<0.05	15 days	3 days	<0.05

CONCLUSION

CONCLUSION

1) This study shows that the short term efficacy and safety of endovenous ablation and open surgery are similar in the treatment of varicose veins.
2) Endovenous ablation presents with lesser post operative morbidity in terms of post operative pain, bruising and hospital stay which was significantly higher in HL/S group.
3) Both the treatments are equally safe and efficient in eliminating great saphenous vein reflux, thereby alleviating symptoms and signs of GSV varicosities and improving quality of life.
4) Symptom reduction and cosmetic improvement after endovenous procedures are slightly better when compared to surgery.
5) Endovenous procedures can be done as a day care procedure which allows a rapid return to normal activity and also earlier return to work.

6) Endovenous procedures has lower complication rates than surgery, particularly in respect of saphenous parasthesia wound problems, hematoma formation and bruising.
7) Although it might appear that EVLA has some advantages over RFA in terms of frequency of complications like bruising, skin burns and “cord like pulling sensation”, there is no clear evidence that one or the other should be the preferred procedure.
8) Given the choice, most patients will choose endovenous procedures instead of an operation with a cut in the groin and vein stripping.
9) This will become particularly true if the long term outcomes, including the recurrence rates, remain equal.
10) Considering the ease and comfort of the procedure, with fewer peri procedural complications and equivalent short and midterm results the endovenous procedure definitely has an edge over the traditional open procedure.

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MASTER CHART

sl no	Name	age	sex	IP no	LIMB	CEAP	Procedure	Peri-OP Events			Hospital stay in days	Follow-up																			
								bruising	saphenous paraesthesia	burns		Pain				CEAP				GSV Status				Ulcer Size				DVT			
												A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
1	Kadarkarai	42	M	45322	R	C2	EVLT	-	-	-	3	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
2	Mani	36	M	45623	R	C2	Trendelenburg	yes	-	-	7	yes	yes	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
3	Udhayasankar	35	M	3786	R	C2	Trendelenburg	-	-	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
4	Baskar	29	M	4075	L	$C2C4_a$	Trendelenburg	yes	-	-	7	yes	-	-	-	C_oC4_a	C_oC4_a	C_oC4_a	C_oC4_a	-	-	-	-	-	-	-	-	-	-	-	-
5	Anandh	33	M	4670	L	C2C6(4cm)	EVLT	-	-	-	3	-	-	-	-	C_oC6	C_oC6	C_oC5	C_oC5	X	X	X	X	4cm	2cm	-	-	-	-	-	-
6	Mani	63	M	3197	L	C2C6(2cm)	EVLT	-	-	-	3	-	-	-	-	C_oC6	C_oC6	C_oC5	C_oC5	X	X	X	X	2cm	1cm	-	-	-	-	-	-
7	Malaiyatri	50	M	6513	L	C2	Trendelenburg	yes	yes	-	10	yes	yes	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
8	Selvaraj	33	M	3524	L	C2	Trendelenburg	yes	-	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
9	Mhd.Habeeb	33	M	6035	R	C2	EVLT	-	-	-	2	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
10	Ganesh Kumar	35	M	9669	R	C2	EVLT	-	-	-	2	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
11	Sheriff	40	M	230/12	L	C2	RFA	-	-	-	3	yes	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
12	Britto	36	M	9757	L	$C2C4_a$	Trendelenburg	-	-	-	7	yes	-	-	-	C_oC4_a	C_oC4_a	C_oC4_a	C_oC4_a	-	-	-	-	-	-	-	-	-	-	-	-
13	Anandraj	55	M	124/12	R	$C2C4_a$	RFA	-	-	-	3	-	-	-	-	C_oC4_a	C_oC4_a	C_oC4_a	C_oC4_a	X	X	X	X	-	-	-	-	-	-	-	-
14	Purushotaman	54	M	15865	L	C2	EVLT	-	-	-	2	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
15	Elangovan	30	M	822/08	L	C2	RFA	-	-	-	2	yes	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
16	Soundararaj	32	M	16682	L	C2	Trendelenburg	yes	yes	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
17	Karunanidhi	36	M	16504	L	C2	RFA	-	-	-	2	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
18	Chandrasekar	55	M	16895	L	C2	RFA	-	-	-	2	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
19	Senthil kumar	26	M	17888	R	C2	EVLT	-	-	-	1	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
20	Muthukrishnan	30	M	17883	L	C2	Trendelenburg	-	-	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
21	Muthuraj	42	M	9522	L	C2	EVLT	-	-	-	2	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
22	Ravi	25	M	15811	L	C2	Trendelenburg	-	yes	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
23	Rathina sekar	22	M	14572	L	C2	Trendelenburg	-	-	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
24	Ravichandran	45	M	21121	R	$C2C4_a$	Trendelenburg	-	-	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-

25	Saiadammal	41	F	20418	R	C2	RFA	-	-	yes	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
26	Ramesh	48	M	14812	R	C2	RFA	-	-	-	2	-	-	-	-	C_o	C_o	C_o	C_o	X	X	X	X	-	-	-	-	-	-	-	-
27	Britto	21	M	18512	L	C2	Trendelenburg	-	-	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
28	Pandurangan	48	M	22604	R	$C2C4_a$	Trendelenburg	-	-	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
29	Senthamarai	48	M	16324	L	C2	RFA	-	-	-	5	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-
30	Muthukumar	35	M	191/12	L	C2	Trendelenburg	yes	-	-	7	yes	-	-	-	C_o	C_o	C_o	C_o	-	-	-	-	-	-	-	-	-	-	-	-

PROFORMA

PROFORMA

Case No:

Name: Age: Yrs Sex:

I.P.No:

Occupation:

Address:

Contact No:

Date of Admission:

Date of Surgery:

Date of Discharge:

Presenting History: (Venous Clinical Severity Scoring)

	Duration	Onset	None-0	Mild-1	Moderate-2	Severe-3
Pain						
Varicose veins						
Edema legs						
Skin pigmentation						
Inflammation						
Induration						
Ulcer						

Past History:

	Yes	No
H/O trauma		
H/O previous surgery		
H/O prolong immobilization		
H/O previouo DVT		
H/O DM/HT/PTB		
H/O drug intake		

Family History of Varicose Veins: Y/N

Treatment History:

Conservative Modality Tried: Y/N

Smoker: Y/N

General examination:

BMI- CVS:

PR- RS:

BP- P/A:

Local Examination:

Limb involved: Right/Left

CEAP:

Ulcer: Size –

Site –

Edge –

Floor –

Peripheral pulses:

ABI:

INVESTIGATIONS:

Hb%

TC

DC

ESR

Blood- urea

Blood-sugar

Sr.Creatinine

CXR

ECG

DUPLEX SCAN:

SFJ reflux - Y/N - time

SPJ reflux - Y/N - time

Perforators - Sites Reflux - Y/N

GSV diameter at - SFJ Mid thigh Below Knee

GSV anamolies -

Deep vein status -

TREATMENT:

	EVENTS	SURGERY	RFA(VNUS CLOSURE FAST)	EVLT(1470nm LASER)
1	Anaesthesia			
2	Procedure	High Ligation and Stripping(Trendelenburg)	Port of entry:	Port of entry:
			GSV length ablated:	GSV length ablated:
			RF cycles:	Pull back speed:
			Total treatment time:	Total treatment time:
			Treatment time:	Treatment time:
			Treatment power:	Treatment power:
3	Peri operative events:			
	a)Bruising			
	b)saphenous parasthesia			
	c)skin burns			
4	Hospital stay in days			

FOLLOW UP:

	Immediate Post OP(72 hrs)	2weeks-1month	4-6 months	10-12 months
Pain				
CEAP				
Ulcer size				
GSV status				
DVT				